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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,275	06/08/2005	Hisao Masai	082368-001100US	2728
20350	7590	11/30/2006	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			SWOPE, SHERIDAN	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/507,275

Applicant(s)

MASAI ET AL.

Examiner

Sheridan L. Swope

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>0904/0506/0906</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election, without traverse, of Invention I, Claims 1-3 and 8, in their response of September 22, 2006 is acknowledged. Claims 1-3 and 8 are pending and are hereby examined.

Priority

The priority date of the instant invention is taken to be June 8, 2005, the filing date of the instant application. If Applicants wish to perfect their claim to priority documents PCT/JP03/02918, filed March 12, 2003, and JP 2002-067702, filed March 12, 2002, translations of said documents should be filed.

Information Disclosure Statement

The foreign patent documents listed on the Information Disclosure Statement filed September 22, 2006 have not been considered because said documents have not been submitted by Applicant. Any future rejection based on said documents will not be considered to be a new grounds for rejection.

Title-Objections

The title is objected to for being too long and not being descriptive of the elected invention.

Claims-Objections

The claims are objected to for not beginning with a sentence of which the claims are an object, i.e., "We claim" or "The claims are".

Claim Rejections - 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the following reasons.

For Claim 1(a), the phrase “functionally equivalent” renders the claim indefinite. Neither the claims nor the specification provide a definition for said phrase. The skilled artisan would not know the metes and bounds of the recited invention. Claims 2 and 3, as dependent from Claim 1, are indefinite for the same reasons.

Claim 3 is rendered indefinite by the fact that said claim fails to further limit the claim from which it depends.

Claim 8(a) is indefinite and confusing. The skilled artisan would not know the metes and bounds of the recited invention. For purposes of examination, it is assumed that Claim 8(a) is meant to recite a substrate protein comprising SEQ ID NO: 1.

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Claims 1-3 and 8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detecting in vitro phosphorylation of Mcm2, as set forth by SEQ ID NO: 1, by the protein encoded by GST-TAT-ASK(minimum)-HA-huCdc7 (Example 7) using the anti-phosphopeptide antibody of Example 6, does not reasonably provide

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enablement for detecting phosphorylation of SEQ ID NO: 1 on Ser¹⁷, by the protein encoded by GST-TAT-ASK(minimum)-HA-huCdc7 (Example 7) using the anti-phosphopeptide antibody of Example 6. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In regards to this enablement rejection, the application disclosure and claims are compared per the factors indicated in the decision *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). These factors are considered when determining whether there is sufficient evidence to support a description that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. The factors include but are not limited to: (1) the nature of the invention; (2) the breath of the claims; (3) the predictability or unpredictability of the art; (4) the amount of direction or guidance presented; (5) the presence or absence of working examples; (6) the quantity of experimentation necessary; (7) the relative skill of those skilled in the art. Each factor is here addressed on the basis of a comparison of the disclosure, the claims, and the state of the prior art in the assessment of undue experimentation.

Claims 1-3 encompass a method for detecting the activity of any Cdc7/ASK complex kinase activity by measuring phosphorylation of only Ser¹⁷ of SEQ ID NO: 1 using an anti-phosphopeptide antibody. Claim 8 is so broad as to encompass a kit for measuring the activity of any Cdc7/ASK complex kinase activity, wherein the kit comprises the protein of SEQ ID NO: 1 and an antibody that recognizes only phospho-Ser¹⁷ of said protein. As would be known to those of skill in the art, the success of the recited method depends on the specificity of the antibody used for detection of phosphorylation. It is acknowledged that the antibody described in

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Example 6 binds to the phosphorylated peptide Arg-Gly-Asn-Asp-Pro-Leu-Thr-Ser_(p)-Ser but not the non-phosphorylated peptide (Fig 2). However, neither the specification nor the prior art provide evidence that said antibody binds only to the phosphorylated serine residue at position 17 of SEQ ID NO: 1 to the exclusion of other phosphorylated residues in SEQ ID NO: 1.

Using a radioactive assay, Cho et al (2006) teach that cdc7 kinase phosphorylates SEQ ID NO: 1 primarily on residue Ser⁴⁴ (Ser⁵³ therein; pg 11242, para 3). In fact, Cho et al teach that a peptide comprising Ser¹⁷ of SEQ ID NO: 1, M2C, was not phosphorylated (Fig 2; pg 11522, para 2). The skilled artisan would know that if Ser⁴⁴ is phosphorylated to a much greater extent than Ser¹⁷ of SEQ ID NO: 1, more likely than not, the antibody of Example 6 will detect SEQ ID NO: 1 phosphorylated on residue Ser⁴⁴. Therefore, the specification fails to enable the skilled artisan to make and use the recited invention, a method for detecting the activity of Cdc7/ASK complex kinase activity by measuring only phosphorylation of Ser¹⁷ of SEQ ID NO: 1 using an anti-phosphopeptide antibody. The specification also fails to enable a kit for performing said method.

Written Description

Claims 1-3 and 8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims 1-3 are directed to a genus of methods for detecting the activity of any Cdc7/ASK complex kinase activity by measuring phosphorylation of only Ser¹⁷ of SEQ ID NO: 1 using an anti-phosphopeptide antibody. Claim 8 is directed to a genus of kits for performing said method,

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wherein the kit comprises an antibody that recognizes only phospho-Ser¹⁷ of said protein. The specification teaches the no representative species of such methods or kits. Moreover, the specification fails to describe any representative species by any identifying characteristics or properties other than the functionality of being a method for detecting the activity of any Cdc7/ASK complex kinase activity by measuring phosphorylation of only Ser¹⁷ of SEQ ID NO: 1 using an anti-phosphopeptide antibody as well as a kit for performing said method. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Final Comments

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheridan Lee Swope, Ph.D.
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SHERIDAN SWOPE, PH.D.
PRIMARY EXAMINER